



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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PURGED RAK

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

August 13, 1999

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 99 - 42

Raymond C. Augustine
President
Augie's, Inc.
1900 W. County Road C
Roseville, Minnesota 55113

Dear Mr. Augustine:

The Food and Drug Administration (FDA) conducted an inspection of your seafood salad and seafood sandwich operations at the above facility on May 10, 1999, to determine your compliance with the Seafood HACCP and GMP regulations denoted in Title 21, Code of Federal Regulations, Parts 123 and 110, respectively (21 CFR 123 and 110). At the conclusion of that inspection, the FDA investigator issued a list of inspectional observations on form FDA-483 and discussed them with you.

The FDA-483 listed the following violations:

1. Your firm does not have HACCP plans to control the following food safety hazards: pathogen growth due to time/temperature abuse for the ready-to-eat tuna macaroni salad and pathogen survival through cooking for the breaded fish sandwiches [21 CFR 123.6(b)].

Page Two

Raymond C. Augustine
August 13, 1999

2. Your firm's HACCP plans for Tuna Salad sandwich products do not include a critical control point for the cooler storage of the tuna salad mix to control the food safety hazard of pathogen growth [21 CFR 123.6(c)(2)]. In addition, your HACCP plan for Tuna Salad Sandwich with Lettuce does not include a critical control point for the cooler storage of the finished product.
3. Your firm's HACCP plan for Tuna Salad sandwich does not include the procedures and frequency for monitoring the critical control point at finished product storage in order to control the food safety hazard of pathogen growth (listed in the plan as micro growth [21 CFR 123.6(c)(4)]).
4. You are not adequately monitoring sanitation conditions and practices during processing [21 CFR 123.11(b)]. During the May 1999 inspection our investigator observed insanitary conditions and practices at your facility. These conditions and practices include: raw ground beef thawing in a pool of blood on each of two shallow trays above and near ready-to-eat products within the south walk-in cooler; employees working in their street clothing and wearing earrings; and lack of adequate pest control devices.
5. You are not maintaining sanitation control records that document monitoring and corrections [21 CFR 123.11(c)].

Please refer to the form FDA-483 on May 10, 1999, for a more detailed listing of the objectionable findings. The listing of these inspectional observations is not intended to be an all-inclusive listing of the violations at your facility. As the most responsible individual at your facility, you are responsible to ensure your operations are in compliance with both local and federal requirements. These findings cause the seafood products manufactured at your facility to be adulterated according to Section 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act) in that they were manufactured and held under conditions whereby they may have been rendered injurious to health. The adulteration of a previously unadulterated food after shipment in interstate commerce and the shipment of an adulterated food in interstate commerce is prohibited by Section 301 of the Act.

Page Three

Raymond C. Augustine
August 13, 1999

Within 15 working days of receipt of this letter please provide a written response detailing the actions you have taken to correct these violations and prevent their recurrence. Also include a timeline as to the projected completion dates for these corrective actions, so we may re-inspect to verify the effectiveness of your corrective action plan.

If you fail to take timely corrective actions, FDA may initiate legal actions against you and/or your products in the form of an injunction or seizure.

Additionally, the listed critical control point (CCP) (Lettuce) in your HACCP plan for Tuna Salad Sandwich with Lettuce is not appropriate. The "Lettuce" CCP should be changed to a "Receiving" CCP, followed by a list of the raw vegetable ingredients.

Your response and any questions you may have regarding this matter may be directed to Compliance Officer Thomas P. Nelson at the address indicated on the letterhead, or (612) 33404100 ext. 177.

Sincerely,

A handwritten signature in black ink, appearing to read "James A. Rahto", with a long horizontal flourish extending to the right.

James A. Rahto
Director
Minneapolis District

TPN/ccl